

## REMARKS

Claims 12-27 have been cancelled and new claims 28-42 have been added. The above amendments to the claims have been made to put the application in better condition for allowance. No new matter has been added.

### Response to Rejections under 35 U.S.C. § 103

Claims 12, 13, 15, 16, and 18-22 were rejected under 35 U.S.C. §103(a) as being obvious over Van Leuven (U.S. 4,267,168) in view of Bringloe (U.S. 4,765,478). The Examiner asserts that Van Leuven discloses a composition which is useful as a lubricant (i.e. glycerin- see col. 6, lines 1-7) to be used during delivery at the time of birth (col. 6, lines 52 to 54) and does not contain alkali metal salts of metaphosphates (col. 6, lines 26 to 36). The Examiner acknowledges that Van Leuven does not disclose that the composition is in the form of a gel, but cites Bringloe as disclosing that hydroxymethyl cellulose is a known gelling agent in topical compositions.

Applicants submit that, as amended, the claims require the step of introducing a composition comprising a physiologically acceptable organic lubricant consisting essentially of a polyacrylic acid, a thickener, a humectant, and no alkali metal salts of metaphosphates, in an effective amount into the birth canal of the mother, wherein said composition is in the form of a paste, gel, cream, suppository, or foam. Neither Van Leuven nor Bringloe discloses the use of a polyacrylic acid. Therefore, based on the above, Applicants submit that the combination of Van Leuven and Bringloe does not render the present claims obvious.

Claim 14 was rejected under 35 U.S.C. §103(a) as being obvious over Van Leuven (U.S. 4,267,168) in view of Bringloe (U.S. 4,765,478), and further in view of Hardy (U.S. 4,981,686). The Examiner asserts that Hardy discloses lubricants selected from petrolatum, coconut oil, lanolin, mineral oil, and stearyl alcohol, thus it would have been obvious to add a natural or synthetic oil, fat or wax to the composition taught by the combination of Van Leuven and Bringloe with Hardy. Applicants submit that none of the above cited references discloses the use of a polyacrylic acid. Therefore, based on the above, Applicants submit that the combination of Van Leuven, Bringloe and Hardy does not render the present claims obvious.

Claims 12, 13, 15, 16, 18-20 and 22 were rejected under 35 U.S.C. §103(a) as being obvious over Kasahara (U.S. 3,971,848) in view of Bringloe (U.S. 4,765,478). The Examiner asserts that Kasahara discloses a compositing comprising a physiologically acceptable organic lubricant and no alkali metal salts of metaphosphates, optionally containing carboxymethyl cellulose, into the birth canal of a woman (see col. 5, lines 16-51). Applicants submit that none of the above cited references discloses the use of a polyacrylic acid. Therefore, based on the above, Applicants submit that the combination of Kasahara and Bringloe does not render the present claims obvious.

Claim 14 was rejected under 35 U.S.C. §103(a) as being obvious over Kasahara in view of Bringloe, and further in view of Hardy. The Examiner asserts that Hardy

discloses lubricants selected from petrolatum, coconut oil, lanolin, mineral oil, and stearyl alcohol, thus it would have been obvious to add a natural or synthetic oil, fat or wax to the composition taught by the combination of Kasahara and Bringloe with Hardy. Applicants submit that none of the above cited references discloses the use of a polyacrylic acid. Therefore, based on the above, Applicants submit that the combination of Kasahara, Bringloe, and Hardy does not render the present claims obvious.

Claim 21 was rejected under 35 U.S.C. §103(a) as being obvious over Kasahara in view of Bringloe, and further in view of Van Leuven. The Examiner asserts that Kasahara discloses that the composition may contain an antiseptic but is silent as to the amount of antiseptic. Applicants submit that none of the above cited references discloses the use of a polyacrylic acid. Therefore, based on the above, Applicants submit that the combination of Kasahara, Bringloe, and Van Leuven does not render the present claims obvious.

Claim 23 was rejected under 35 U.S.C. §103(a) as being obvious over Kasahara in view of Bringloe, and further in view of JP46-24256 (JP '256). The Examiner asserts that Kasahara discloses applying a composition to the birth canal to ease childbirth, wherein the composition comprises sodium polyacrylate (see col. 5, lines 40-41). The Examiner acknowledges that sodium polyacrylate is not present as a lubricant, but cites JP '256 as disclosing that sodium (or ammonium) polyacrylate is useful as a lubricant during birth. Claims 24-27 were rejected under 35 U.S.C. §103(a) as being obvious over Kasahara in view of Bringloe and JP '256 as applied to claim 23, and further in view of Van Leuven and Spruce et al. (WO 01/74359) and Gold (U.S. 5,342,617). The Examiner asserts that Kasahara discloses that the composition may comprise a

cellulose such as carboxymethyl cellulose (col. 5, line 40) and also glucose (col. 5, line 43-45). The Examiner cites Spruce as disclosing that glucose is a known isotonicizing substance (page 28, lines 10-11). The Examiner cites Van Leuven as disclosing that the humectants propylene glycol and glycerin are used in compositions which act as lubricants during birth. The Examiner asserts that it would have been obvious to add propylene glycol and/or glycerin and that one of ordinary skill would have been motivated to do so because humectants provide soothing action on tender tissue and some bacteriocidal activity. With regard to claim 25, the Examiner asserts that Kasahara discloses adding carboxymethylcellulose (col. 5, lines 39-42). With regard to claim 26, the Examiner asserts that Van Leuven discloses polypropylene glycol and glycerin (abstract). With regard to claim 27, the Examiner acknowledges that none of the cited references disclose hydroxyethyl cellulose, but asserts that one of ordinary skill would expect it to function in an equivalent manner to carboxymethyl cellulose because both are used as gelling agents in human tissue lubricants as evidenced by Gold (see col. 1, lines 21-28).

Applicants submit that, as amended, the present claims are non-obvious over any combination of the cited references for the following reasons. Kasahara, Bringloe, and JP 46-24256, alone or in combination, do not render obvious an organic lubricant consisting essentially of a polyacrylic acid, a thickener and a humectant. Kasahara's composition obligatorily contains large amounts of alginates and fucoidin as organic substances having a lubricant effect. These substances are essential to the composition of Kasahara, but are not contained in the composition used in the present claims. Indeed, because addition of alginates often leads to the formation of unwanted

discolorations or precipitates as is disclosed in paragraph [0024] of post-published U.S. application serial No. 11/718,995, it materially affects the basic and novel characteristics of the composition for use in the present claims.

The enclosed declaration signed by the inventor, Dr. Andreas Schaub, details unexpected experimental results when using the presently claimed method as well as Dr. Schaub's expert opinion regarding significant differences between animal and human delivery.

Dr. Schaub refers to the peer-reviewed research article entitled "Obstetric gel shortens second stage of labor and prevents perineal trauma in nulliparous women: a randomized controlled trial on labor facilitation" (Schaub et al. *J. Perinat. Med.* 2008, 36, 129-135), which discloses clinical trials reporting significantly reduced labor time using the presently claimed method. In fact, the mean total labor duration (stages 1 and 2) in women having a birth from an occipito-anterior position without interventions (i.e. Caesarean section, vaginal operative procedures, or Kristeller maneuver) was reduced from  $297.05 \pm 21.42$  minutes (group A-I) when obstetric gel was not used to  $248.14 \pm 25.66$  minutes (group B-I), when using the presently claimed gel. Thus, a total reduction of about 49 minutes was obtained by using the inventive composition, provided that the women did not receive any medical interventions (cf. page 132, left column in combination with Table III). Further, the paper also shows that the mean total labor duration is even more reduced in subgroups of the above-mentioned trial are investigated (cf. Geissbuhler et al., *Gynakologisch-Geburtshilfliche Rundschau* 2008, 48, 111-204).

Further, it was found that the mean total labor duration in a subgroup of patients neither receiving epidural anesthesia (EDA) nor amniotomy (AMN) was significantly shortened by 106 minutes (from 294 minutes to 188 minutes), when the obstetric gel of the present invention was employed. Simultaneously, a reduction of the dilation period (stage 1) and the expulsion period (stage 2) was also observed for other subgroups of patients depending on the use of EDA and/or AMN.

Dr. Schaub also indicates that the use of 80g of KY® jelly does not suggest the significantly shortened total labor duration achieved using the presently claimed invention. In Dr. Schaub's clinical trial, just 22g of the presently claimed obstetric gel resulted in a significant reduction in the duration and frictional force during birth. The almost four-fold reduction in volume/amount of lubricant require in human vaginal child birthing using the presently claimed obstetric gel is an additional advantage because the risk of complications for both the mother and the child during labor are reduced.

With regard to the Examiner's assertion that the combination of Kasahara and JP '256 would render obvious methods of using formulations intended for veterinary applications to human birthing, Dr. Schaub opines that there are significant differences between animal and human delivery due to different anatomical and functional factors. These differences are such that a liquid composition as proposed by Kasahara and JP 46-24256 are not at all appropriate in human vaginal child birthing. Dr. Schaub refers to the full-body hair coverage of the animal fetus, the presence of natural lubricant in animals, the occurrence of both translational and rotational motions of the human fetus when passing the birth channel, and the different consistency of the amniotic fluid in

animal and human subjects, and opines that formulations intended for use in animal delivery would not be appropriate for human use.

Further, a lubricant for use in human vaginal child birthing must exhibit, inter alia, a high viscosity for preventing an aspiration of the lubricant into the lungs of the fetus and for preventing an infiltration of the lubricant into the motherly blood circuit (risk of amniotic fluid embolism), a high capacity for binding water, a high water resistance, a slightly acidic pH for preventing mucous membrane irritations, transparency for permitting a diagnosis of the condition of the fetus, etc. Consequently, in order to reduce the risk of side effects, the use of liquids as a lubricant in human vaginal child birthing is not desirable, whereas in animals big volumes of a liquid can be used without any difficulty for preventing adhesion of the fully-haired animal fetus in the birth channel.

Dr. Schaub's declaration provides further experimental results demonstrating that the presently claimed composition for use has the unexpected and surprising advantage of reducing obstetrically relevant vaginal bacteria without the use of known bactericidal substances or preservatives. Based on these results, Dr. Schaub opines that the presently claimed method has the unexpected and surprising ability to prevent infection complications such as endomyometritis or neonatal infection during human birth.

Applicants submit that based on the above reasoning, data, and expert opinion, the presently claimed method is not rendered obvious by any combination of the cited references. The claimed method has demonstrated clinical efficacy which is unexpected and significantly better than the methods in use at the time of the invention. Further, the formulation for use in the claimed method has surprising properties in that it

is capable of reducing infections during birth. Such infections can result in complications during and after birth and there has been a long-felt need to reduce infections and reduce labor time. Therefore, Applicants submit that new claims 28-42 are unobvious for the above reasons and respectfully request that they be allowed.

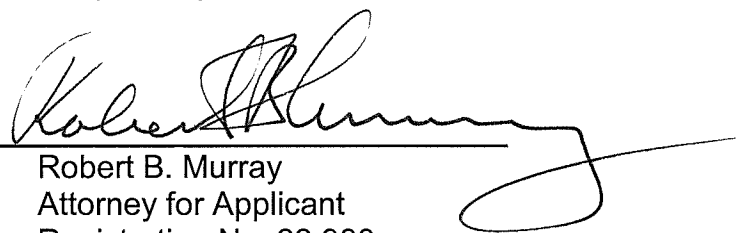
### Conclusion

In view of the foregoing, it is submitted that the present application is now in condition for allowance. Reconsideration and allowance of the pending claims are requested. The Director is authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135. A Notice of Allowance is respectfully requested. Early and favorable action is awaited.

The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

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Enclosures: 1) Declaration signed by Dr. Schaub and 2) Schaub et al. *J. Perinat. Med.* 2008, 36, 129-135  
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